

REMARKS

Claims 6 and 23-29 were pending in the present application. By virtue of this amendment, claims 6 and 24-29 have been amended. Support for the amendments is found throughout the specification, *e.g.*, at page 16, lines 32-34. Amendment of certain claims is not to be construed as a dedication to the public of any of the subject matter of the claims as previously presented. Claims 6 and 23-29 are pending, and no claim has been allowed.

Formal Matters

Applicants gratefully acknowledge the grant of the Request for Continued Examination.

Applicants regret the inadvertent misnumbering of the claims in the Response to Final Action mailed April 16, 2003. Applicants appreciate the Examiner's renumbering of the claims in the Action mailed August 29, 2003.

The currently pending claims are also amended herein to address the issues under 35 U.S.C. § 112, second paragraph, as identified by Examiners Schwadron and Chan in the interview.

Summary of Examiner Interview

Applicants are deeply appreciative of the time and effort provided by Examiner Schwadron and Supervisory Examiner Chan in the recent Examiner Interviews of January 14, 2004 and January 22, 2004. Applicants believe the Interviews were very productive. The summary of the Interviews is as follows: On January 14, 2004, the undersigned and Examiners Schwadron and Chan discussed the rejections under 35 U.S.C. §§ 102(e) and 103 (a) at length. No agreement was reached on the specificity of the claimed antibodies, and a second Interview was deemed necessary. On January 22, 2004, the undersigned and Examiners Schwadron and Chan again discussed the asserted prior art rejections. Examiners Schwadron and Chan proposed a number of amendments to address the outstanding rejections as well as a number of 35 U.S.C. § 112, second paragraph issues

identified. All parties agreed that the proposed amendments would overcome the outstanding rejections.

Rejection Under 35 U.S.C. §112, First Paragraph

Claim 29 is rejected under 35 U.S.C. § 112, first paragraph as allegedly failing to comply with the written description requirement. According to the Action, there is no support for the recitation of “peptide of at least 8 amino acids” in claim 29, and thus the claimed invention constitutes new matter. Applicants traverse this rejection.

Applicants respectfully submit that the specification provides adequate support for a kit comprising a “peptide of at least 8 amino acids” as recited in claim 29. First, kits are disclosed throughout the specification as including 312C2 proteins and fragments or peptides. For example, at page 4, line 25-26, the specification states that the “invention also includes a kit containing a substantially pure 312C2 or fragment” (emphasis added). At page 46, lines 22-25, the specification discloses using “312C2 proteins, fragments thereof, peptides, and their fusion products in a variety of diagnostic kits and methods for detecting the presence of another 312C2 or binding partner” (emphasis added). The specification goes on to disclose polypeptides and fragments or segments of polypeptides as “encompassing a stretch of amino acid residues of at least about 8 amino acids.” See the specification at page 8, lines 29-31. Again at page 47, lines 17-19, the specification discloses the use of 312C2 or fragments in diagnostic applications. Such disclosure unambiguously encompasses the use of fragments of 312C2 includes a fragment of at least 8 amino acids in kits, and therefore, the specification provides adequate written description for a kit comprising a 312C2 peptide of at least 8 amino acids.

In view of the above, Applicants respectfully submit that the rejection is overcome and request its withdrawal.

Rejection Under 35 U.S.C. § 102 (e)

Claims 6 and 26 are rejected under 35 U.S.C. § 102 (e) as allegedly being anticipated by Baum et al., U.S. Patent No. 5,457,035. According to the Action, Baum teaches a monoclonal antibody that binds a protein, *i.e.*, OX40-L, that shares a five amino acid region of homology with

the disclosed novel protein, 312C2. The Action asserts that an antibody which binds the five amino acid region, *i.e.*, amino acids 139-143, of OX40-L would bind the same sequence in intact SEQ ID NO: 4, thus Baum anticipates the claimed antibodies. Applicants traverse this rejection.

Baum fails to disclose antibodies that are specific for 312C2 protein, and therefore this reference fails to anticipate the claimed antibody. Applicants respectfully submit that claims as amended herein clarify that the claimed antibody specifically binds the novel protein 312C2 and not other proteins. Therefore, the claimed antibodies would not specifically bind OX40-L, and therefore are not anticipated by the antibodies disclosed by Baum.

In view of the foregoing, Applicants respectfully request reconsideration and withdrawal of the rejection under 35 U.S.C. § 102 (e).

Rejection Under 35 U.S.C. § 103 (a)

Claims 6 and 23-28 are rejected under 35 U.S.C. § 102 (e) as allegedly being unpatentable by Baum et al., U.S. Patent No. 5,457,035 in view of Godowski et al., U.S. Patent No. 5,709,858. According to the Action, Baum teaches a monoclonal antibody that binds a protein, *i.e.*, OX40-L, that shares a five amino acid region of homology with the disclosed novel protein, 312C2. The Action asserts that an antibody which binds the five amino acid region, *i.e.*, amino acids 139-143, of OX40-L would bind the same sequence in intact SEQ ID NO: 4. The Action further asserts that Godowski teaches antibody fragments, humanized antibodies, labeled antibodies and immobilized antibodies wherein the molecules are produced using art known methods and wherein the reagents have well known uses. According to the Action, it would be *prima facie* obvious to create the claimed invention in view of these teachings. Applicants traverse this rejection.

The cited combination of references fails to teach each and every element of the claimed invention. First, the currently pending claims relate to antibodies and antigen binding fragments thereof that specifically bind the novel protein 312C2, and not other proteins. Baum, on the other hand, discloses antibodies that are specific for the unrelated OX40-L protein and has no disclosure regarding antibodies that bind 312C2. Because the claimed antibodies would not specifically bind OX40-L protein disclosed in Baum, Baum fails to teach the antibody with the claimed specificity. Similarly, Godowski provides no disclosure regarding antibodies and antigen binding fragments

thereof that specifically bind 312C2 while not specifically binding other proteins. Therefore, Godowski fails to remedy the deficiencies in Baum. In the complete absence of any teachings regarding antibodies or antigen binding fragments thereof that specifically bind 312C2, the cited references fail to render the claimed antibodies *prima facie* obvious.

In view of the foregoing, Applicants respectfully request reconsideration and withdrawal of the rejection under 35 U.S.C. § 103 (a).

CONCLUSION

In view of the above, each of the presently pending claims in this application is believed to be in immediate condition for allowance. Accordingly, the Examiner is respectfully requested to withdraw the outstanding rejection of the claims and to pass this application to issue. If it is determined that a telephone conference would expedite the prosecution of this application, the Examiner is invited to telephone the undersigned at the number given below.

In the event the U.S. Patent and Trademark office determines that an extension and/or other relief is required, applicant petitions for any required relief including extensions of time and authorizes the Commissioner to charge the cost of such petitions and/or other fees due in connection with the filing of this document to Deposit Account No. 03-1952 referencing docket no. 140942000510. However, the Commissioner is not authorized to charge the cost of the issue fee to the Deposit Account.

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Respectfully submitted,

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